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Ryan

I understand that you have been discussing the future of the Integrated Risk Information System (IRIS), housed in the National Center for Environmental Assessment (NCEA) in EPA's Office of Research and Development (ORD), and I want to express my strong support for this critical Agency program. The IRIS program is essential to the statutory mission of the EPA – several regional and program offices, particularly OLEM, OAR, and OW, rely exclusively on its assessments or ancillary products of its assessments. These collaborations extend to states and other agencies as well – DoD, for example uses IRIS to inform and set policy across it units. ORD has made several key changes in IRIS that are clearly demonstrating impact. The IRIS program is poised to deliver as a result of the significant enhancements and management changes undertaken over the last several years, which will enable it to remain critical to successfully supporting Agency actions.

Created in 1985, IRIS assessments identify the potential for a chemical to cause cancer or non-cancer health effects in people. IRIS assessments are not risk assessments or regulatory decisions. The assessments are complex, multidisciplinary evaluations of scientific information, which are developed through a transparent and systematic process with robust, independent peer review. The IRIS Program utilizes a multi-step process which provides multiple opportunities for public, stakeholder, and interagency engagement.

Over the years IRIS has evolved in order to enhance its relevance, increase engagement with its numerous stakeholders, remain responsive to scientific advances, and deliver public health relevant assessments. Assessments have grown complex, lengthy, and controversial. Even with these challenges, IRISremains the top tier source of toxicity information used by EPA and other agencies to inform national standards, clean-up levels at local sites, and set advisory levels. IRIS assessments inform decisions under the Clean Air Act, Safe Drinking Water Act, CERCLA/Superfund, and TSCA. No other program in the country has the capacity to provide this type of service – objectively and independent of bias and influence. There is no functional substitute for IRIS. Absent IRIS, every regulatory body will have to develop its own processes to conduct these assessments.

ORD remains committed to increasing the productivity of the IRIS Program in order to provide more high-quality assessments, while maintaining the scientific integrity and transparency of assessments. As part of these efforts, ORD has recently replaced NCEA and IRIS leadership. The new NCEA Director, Dr. Tina Bahadori, has significant experience in the chemical industry, and brings knowledge of TSCA, innovative applications of computational toxicology, and exposure science. She also has a proven track record of successful leadership as the former National Program Director for ORD's Chemical Safety for Sustainability research program, and as the Managing Director for the American Chemistry Council's Long Range Research Initiative. At the same time, Dr. Kris Thayer, the new IRIS Program Director, is a recognized national leader in systematic review, automation, and chemical evaluations, all of which are essential in moving the IRIS program into 21st Century risk assessment. The new IRIS Program Director also brings experience in early partner and stakeholder engagement and input, and demonstrated ability to increase capacity and transparency in assessments.

ORD is aware that in recent years the productivity of the IRIS Program has slowed and assessments have taken longer to complete than in the past. Over time, the length and complexity of IRIS assessments increased, reflecting the increased volume and complexity of scientific information along with increased stakeholder engagement. ORD has invested in new Project and Program Management strategies that will improve the ability to appropriately resource IRIS assessments, effectively navigate the assessment milestones, and increase confidence in and reliability of assessment timelines. The Agency took steps to strengthen and streamline the IRIS Program in response to the April 2011 recommendations from the National Research Council (NRC) on the draft IRIS assessment of formaldehyde. The follow-up NRC 2014 report commended EPA's efforts to improve IRIS, noting that "the committee finds that substantial improvements in the IRIS process have been made, and it is clear that EPA has embraced and is acting on the recommendations in the NRC formaldehyde report." Recognizing that EPA is still implementing changes, the NRCnoted that substantial progress has been made in a short time and that "overall the committee expects that EPA will complete its planned revisions in a timely way and that the revisions will transform the IRIS Program."

The Government Accountability Office (GAO) is well aware of the critical nature of the IRIS program to the Agency mission. In the 2017 GAO High Risk Report, GAO stated:

EPA's "ability to effectively implement its mission of protecting public health and the environment is critically dependent on assessing the risks posed by chemicals in a credible and timely manner. Such assessments are the cornerstone of scientifically sound environmental decisions, policies, and regulations under a variety of statutes, such as the Safe Drinking Water Act, the Toxic Substances Control Act (TSCA), and the Clean Air Act. EPA conducts assessments of chemicals under its Integrated Risk Information System (IRIS) program." (p. 417)

ORD has made great strides in meeting the GAOrecommendations for IRIS to be removed from their high-risk list. In the most recent GAO high risk report, the IRIS program improved significantly, meeting two of the five criteria (Leadership Commitment and Monitoring), as well as improving its rankings in Demonstrated Progress and Capacity. Of the seventeen recommendations issued by the GAO since 2008, ORD has successfully closed ten recommendations and is rapidly moving to address the remaining seven.

Beyond being responsive to these important external advisory bodies, the new NCEA/IRIS leadership has proposed a portfolio approach to risk assessment in order to increase the timeliness and productivity of the program to better address the needs of the Agency and other stakeholders. A portfolio approach to risk assessment offers a continuum of products ranging from rapid screening of chemicals to the more complex scientific assessment of a large body of evidence from human and animal studies. This portfolio approach offers a nimble, flexible, and efficient way to draw on new data streams, develop a continuum of risk assessment products, and better meet the needs of stakeholders and decision makers. It also significantly increases the speed, transparency, and access to assessment products and democratizes the process for all stakeholders impacted by decisions.

There is an expectation that TSCA, modernized under the Lautenberg Act, can replace the functions of IRIS. Please note that TSCA addresses chemicals in commerce. It does NOT support other activities such as site cleanups, drinking water evaluations, etc. IRIS provides this support across EPA and for states and tribal nations. IRIS also evaluates naturally-occurring chemicals (like manganese) and chemical degradants. For TSCA, IRIS staff are currently working in direct support of the first 10 chemical assessments, providing chemical specific expertise for scoping and evaluating health hazard information, quality checks for work completed by contractors, and training and assistance in implementing best practices of systematic review and evidence synthesis. IRIS staff are also helping to develop automated software workflows directed at expediting the pace and throughput of chemical assessments. IRIS is aiming to shorten the NCEA chemical evaluation timeline to ~2 years (pre-peer review), more consistent with TSCA timelines.

In closing, EPA's IRIS Program is essential to the Agency'smission to protect public health and the environment. There is no substitute for IRIS. As an Agency, we are well positioned to transform IRIS into the 21st Century assessment program it is poised to become. ORD has achieved similar success in the past with re-vitalizing the Integrated Science Assessment program to meet Congressional Clean Air Act requirements. The new IRIS leadership, with support from the expertise in IRIS and from across ORD, brings the experience necessary to implement many of the necessary changes and show significant progress within the next 12-18

months. A thoughtful and strategic approach to enable IRIS to succeed will bring significant dividends to the Agency. As Science Advisor, I strongly support the IRIS program and its evolving directions.

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